Outcomes in a cohort of 39 geriatric AO/OTA C-type fractures of the distal humerus after open reduction and internal fixation with locking plate constructs

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Tiivistelmä – Referat – Abstract

Retrospektiivisen tutkimuksen tavoitteena on selvittää HUS Töölön Sairaalassa vuosina 2007-2016 lukkolevyosteosynteesillä hoidettujen olkaluun alaosan nivelpintaan ulottuvien murtumien (AO-C-tyyppi) lyhyen ja keskipitkän aikavälin toiminnallisia ja radiologisia tuloksia. Samalla saadaan tietoa epätyydyttävää tulosta ennustavista tekijöistä ja voidaan verrata tuloksia kyynärtekonivelaineistoihin.

Olkaluun alaosan nivelen sisäinen murtuma johtaa hoitamattomana huonon toimintakyvyn tarjoavaan kyynärpähän. Nuorilla hoitolinja on rutiininomaisesti operatiivinen, avoreduktio ja osteosynteesi kyynärnivelen toiminnan palauttamiseksi. Vanhuksilla osteosynteesi on teknisesti haastavaa murtumien mittavammasta pirstaleisuudesta johtuen sekä murtuman kiinnityksen pettämisiä, luutumattomuutta ja jäykkyyttä ajatellaan esiintyvän enemmän kuin työikäisillä. Kyynärnivelen tekoniveltä on tarjottu ratkaisuksi vanhusten murtumien hoidossa. Töölön sairaalan suuri volyymi tarjoaa myös kansainvälisesti merkittävän kokoisen potilasmateriaalin.

Tutkimukseen pyydetään kaikkia 1.1.2007- 30.6.2016 Töölön sairaalassa olkaluun alaosan C-tyypin murtuman vuoksi leikkauksella hoidettuja murtuman syntyhetkellä yli 65-vuotiaita potilaita. Alkuajankohta on valittu siten, että lukkolevyt ovat siihen mennessä vakiinnuttaneet asemansa rutiinihoitona. Soveltuvat potilaat kutsutaan tutkimuskäynnille, jonka yhteydessä yläraajojen toimintakyky tutkitaan kliinisesti sekä vastataan toimintakykymittareiden kysymyksiin. Tutkimuksen päätulosmuuttuja on Oxford Elbox Score (OES) –mittari, joka määrittää kyselylomakkeen avulla kyynärnivelen toimintakyvyn vaikutusta arkielämään. Toissijaisina tulosmuuttujina ovat Mayo Elbow Performance Score (MEPS) –mittari, quick-DASH, kyynärnivelen kliinisesti määritetty toimintakyky ja potilaan subjektiivinen tyytyväisyys kyynärpään toimintaan. Lisäksi otetaan kyynärnivelen rtg-kuvat radiologisten muutosten selvittämiseksi. Potilailta määritetään myös terveen puolen toimintakyky, jolloin kunkin terve puoli toimii vertailuryhmänä. Seuranta-aika tulee olemaan vähintään yksi vuosi vammasta, suurimmillaan noin 8,5 vuotta. Keskeisiä taustatietoja ovat vammamekanismi, murtuman luokka ja vammaan sekä leikkaushoitoon liittyvät komplikaatiot.

Tutkimus julkaistaan kyseisen erikoisalan kansainvälisessä lääketieteen lehdessä. Tutkimuksen tuloksia voidaan hyödyntää määrittämään HUS Töölön sairaalassa käytössä olevia hoitolinjoja kyseisen vammatyypin osalta.

Avainsanat – Nyckelord – Keywords

Olkaluun murtuma, Lukkolevy, Osteosynteesi, Leikkaushoito, Ortopedia

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1 Abstract

Background and purpose – Modern treatment options of distal humerus fractures of active elderly patients are osteosynthesis and total elbow arthroplasty. The evidence of outcomes of ORIF after AO/OTA C-type fractures mostly predates the adoption of locking plates. We evaluated the results of open reduction and internal fixation of these fractures treated exclusively with anatomic locking plates.

Patients and methods – A retrospective cohort of 39 patients aged 65 years or above with ORIF for AO/OTA C-type distal humerus fracture using locking plates was identified. 23 provided follow-up data and 14 attended a follow-up visit. Primary outcome was the Oxford Elbow Score. Secondary outcomes were Mayo Elbow Performance Score, qDASH, satisfaction, range of motion, complications and reoperations.

Results - Mean OES pain was 83 (SD 17), OES function 83 (17) and OES social-psychological 79 (20). Mean total OES was 81 (15). Among the 14 patients who attended a follow-up visit, MEPS was 85 (17), qDASH 19 (16), active arc of motion 119 (19) degrees. MEPS and arc of motion were worse than on the healthy side. One patient had a serious deep infection, 11 patients had at least one reoperation, of which 6 were implant removals and 2 subsequent total elbow arthroplasties.

Interpretation – Distal AO/OTA C-type distal humerus fractures in the elderly can be treated reliably and with good outcomes with ORIF using modern locking plates. The mean qDASH scores are similar to population normal values, but when compared to the healthy arm, single-arm scores indicated somewhat impaired function.

2 Introduction

Fractures of the distal humerus in the elderly are challenging due to poor bone quality and frequent fracture comminution. Modern treatment options include open reduction and internal fixation (ORIF) with locking plates (Shannon et al. 2018) and total elbow arthroplasty (TEA) (Mansat et al. 2013) which can restore joint function and stability.

The surgical outcomes have been reported to be similar in ORIF and TEA, but the complication profiles differ. Reoperations are commonly reported following ORIF, while deep infections after TEA are difficult to manage and many surgeons recommend a permanent limb loading limitation after a TEA (Githens et al. 2014) (Mansat 2013). Nonsurgical treatment with cast immobilisation, also known as a "Bag of bones" treatment has been used in the elderly low-demand patients, with acceptable outcomes considering the patient group (Aitken et al. 2015).

The current literature on outcomes after ORIF in the elderly are largely patient series where non-locking plates have been used (Githens 2014). Biomechanical studies have shown that in poor quality bone, locking plates provide a more rigid fixation than non-locking constructs (Schuster et al. 2008) and the options available with modern anatomic plates technically allow ORIF of almost all types of distal humerus fractures. The outcomes in general adult population support ORIF as the first line treatment (Schmidt-Horlohe et al. 2013), but in the elderly there is a paucity of evidence of outcomes with modern implants to guide treatment choices.

The purpose of the study was to evaluate the results of open reduction and internal fixation of intra-articular, AO/OTA C-type distal humerus fractures treated exclusively with anatomic locking plates, in patients at least 65 years of age at the time of injury.

3 Patients and methods

This was a retrospective cohort study with a patient file review and a clinical or telephone follow-up, after a minimum of 1 year after the injury. The study was approved by the Helsinki and Uusimaa Hospital District ethics committee (HUS/938/2017). Patients attending follow-up gave their informed consent. We used the STROBE statement as a guide.

Inclusion criteria: Age at least 65 years at the time of the injury; AO/OTA C-type distal humerus fracture; ORIF in Helsinki University Hospital (a large academic trauma tertiary center serving a population of 1.5M) between June 2009 and May 2016; ability to answer questionnaires in Finnish. We excluded patients with pathologic fractures. Anatomic locking plates had been adopted to routine use by the start of study period.

Potentially eligible patients were identified from the electronic operating room database, using appropriate ICD-10 code (S42.4) with any surgical procedure code. The hospital records and patient x-rays were reviewed in April 2017 by KK and MS to identify eligible patients. The patient and injury details, course and method of treatment, interventions and adverse effects, clinical progression on outpatient visits after the injury, possible date and cause of injury-related death were extracted from electronic medical records.

Contact details of the patients were obtained from hospital records, national population registry and telephone directories. The patients were approached by letters and telephone. The patients were asked to attend a follow-up appointment for outcome measurements and an x-ray. Those unwilling or unable to visit were asked to participate in a telephone interview. The follow-up took place in May 2017.

Our primary outcome was the Oxford Elbow Score (OES) of the injured arm. The OES is a validated, reliable and responsive 12-item, three-domain (pain, function, social-psychological (s-p)) patient-reported outcome measure, specifically designed and developed for assessing outcomes of elbow surgery (Dawson et al. 2008). Secondary outcomes were the Mayo Elbow Performance Score (MEPS) (Morrey B.F. 1993), Quick Disabilities of Arm and Shoulder and Hand (qDASH) (Beaton et al. 2005) and subjective satisfaction with the function of operated elbow on numeric rating scale 0 to 10 (10 fully satisfied). The active and passive elbow flexion and extension were measured with a goniometer, and forearm pronation-supination was measured with a "Myrin" pro-supinometer (Medema, Solna, Sweden) held in a fist between the 2nd and 3rd fingers. Measurements of the range of motion and MEPS items were also obtained of the contralateral elbow of patients who attended the follow-up visit to give an internal control. Patients interviewed by telephone answered the OES questions, injury side and arm dominance. Radiographs were assessed regarding the primary treatment episode (quality of reduction, appropriate placement of implants as assessed by the senior authors, loss of reduction and complications during the primary follow-up) and at possible subsequent visits (development of osteoarthrosis, migration of implants, other complications).

The surgeries were performed either by or under the direct supervision of an experienced orthopaedic trauma surgeon within a few days of the injury, while open fractures were operated emergently. The usual operative protocol was general anaesthesia, lateral decubitus position with arm support and hanging forearm, ORIF with medial and lateral column fixation with anatomic locking plates placed orthogonally according to the AO principles. 3.5mm LCP Distal Humerus Plates or 3.5/2.7mm VA LCP Distal Humerus Plates (DePuy Synthes, Raynham, USA) were used. Olecranon osteotomies were closed with a K-wire tension band or plate. Cannulated screws, headless compression screws and bioabsorbable pins were used to fix articular fragments as necessary. Postoperative rehabilitation was guided by a physiotherapist. Passive range of motion exercises were begun immediately postoperatively and active exercises after 3 weeks, and load bearing was gradually allowed after 6 weeks. Arm sling was worn for comfort for up to 3 weeks.

During the primary treatment episodes patients were typically followed in the outpatient clinic, including radiographs, at 6 weeks and 12 weeks. Follow-up was continued until union of the fracture was established and adequate function of the upper limb was regained.

For comparisons of means of continuous data, we used Student's T-test to test statistical significance. Significance level was set at p =< 0.05. There was no missing data in the follow-up measurements.

4 Results

We included 39 patients of which 14 attended full follow-up and 9 answered the telephone interview (Figure 1). Mean follow-up time of participating patients was 3.2 years (SD 1.6). Patient demographics, fracture types and injury mechanisms are presented in Table 1.

4.1 Outcomes

For the 23 patients with OES data, mean OES pain was 83 (SD 17), OES function 83 (17) and OES s-p 79 (20). Mean total OES was 81 (15).

Secondary outcomes for the patients (n=14) who attended full follow-up are presented in Table 2. The MEPS and the flexion-extension range of motion were statistically significantly lower in the injured elbows than uninjured sides.

Radiographs were obtained from 14 patients. 4 patients had developed minor osteoarthritic changes. No major late complications were evident on the radiographs.

Factors qualitatively associated with inferior outcomes were nerve injuries and permanent extension deficit over 40 degrees. Qualitatively, the loss of points in MEPS were almost always due to pain, not other factors. Also qualitatively, chronic pain in the elbows without nerve injuries was not associated with identifiable radiographic or surgical factors. Due to sample size and heterogeneity of data, no meaningful statistical analysis of predictors of inferior results was possible.

4.2 Primary treatment episodes

The mean time from injury to first surgery was 2.2 (sd 2.0) days. All patients were treated with primary ORIF and bicolumnar plating. The posterior paratripicital approach with olecranon osteotomy was used in all cases except 1. 35 olecranon osteotomies were closed with K-wires and a tension band, 4 with plate and screws.

4.3 Mortality, reoperations and complications

The 30-day mortality was 2/39 and one-year mortality 4/39. The 30-day mortality was due to causes we interpreted to be related to the injury and treatment: 1 patient died of perioperative myocardial infarction and 1 of pneumonia during post-injury stay in a rehabilitation hospital. During the follow-up period, 8 patients had died from unrelated causes, their mean lifetime after the injury was 2.9 years (SD 1.6) and their mean time from injury to patient file review was 4.3 (2.2) years.

The number of surgeries, reasons for reoperations and description of treatment are given in Table 3.

There was 1 traumatic median and 2 traumatic radial nerve injuries, and 1 major iatrogenic ulnar nerve injury and one ulnar nerve entrapment after the surgery.
There were no minor infectious complications, nor heterotopic ossification.

Of the 10 patients with an open fracture 1 attended the follow-up visit and 2 answered the telephone questionnaire; 5 had died, 1 of a cause related to the injury, 1 could not be reached and 1 was not able to participate.

4.4 Concomitant injuries and joint disease

14/39 patients had concomitant fractures. 5 patients had ipsilateral upper extremity or shoulder fractures (2 proximal humerus and 1 distal radius, 1 clavicle, 1 proximal radius), 2 patients had contralateral upper extremity fractures (proximal humerus and clavicle) 1 patient had a rib fracture and 6 had lower body fractures (2 proximal and 1 distal femur fractures, 2 had a fracture of the acetabulum and 1 proximal tibia fracture). None had pre-existing inflammatory arthritis and 2 had minor osteoarthritic radiographic changes in the fractured elbow.

4 of the 14 patients with concomitant injuries had died during the follow-up period, one within 30 days of injury. They died on average 1.4 (2.2) years post-injury. Compared to 2.9 (1.5) year average lifetime for patients without concomitant injuries who died, no statistically significant ($p=0.22$) difference was found.

4.5 Radiographs during the primary treatment episodes

Review of postoperative radiographs showed that 30/39 fractures had been reduced anatomically, eight with 1-3mm and one with 4-5mm malreduction. 37 patients had appropriate placement of hardware, 2 had suboptimal plate positioning leading to short and non-interdigitating screws.

Radiographic review up to the last follow-up visit of the primary treatment showed that 21/39 fractures and osteotomies had united without complications. 8 fractures had united with no loss of reduction, but the olecranon osteotomy had widened (<5mm) before union. 1 patient had a non-union of the olecranon osteotomy (leading to a re-osteosynthesis of the osteotomy). 6 patients had a minor secondary collapse of the distal humerus, 1 a joint-destroying avascular necrosis (leading to TEA), 1 a loss of reduction (treated with TEA) and 1 a deep infection leading to loss of reduction (which led to eventual resection of distal humerus and proximal ulna). 3 patients had minor and 2 extensive osteoarthritic changes at this point.

5 Discussion

In our series, open reduction and internal fixation of displaced, intra-articular AO/OTA C-type distal humerus fractures of elderly patients in a high-volume trauma center resulted in mean DASH score 19, mean MEPS 85, and mean arc of motion of 119 degrees. DASH scores were similar to those in the general population of the same age (Aasheim et al. 2014), but there was a statistically significant and also likely patient important difference in MEPS and arc of motion compared to the uninjured elbow. The one-year mortality was 4/39.

Strengths of our study include reliable identification of patients from the database of a large volume tertiary referral center, the use of a validated outcome measure of function and reliable hospital record data regarding treatments and mortality. To our knowledge, this is the first published series of elderly patients treated exclusively with anatomic pre-contoured locking plate constructs. Limitations include a relatively low number of patients, lack of preoperative data of function – which we sought to mitigate by the use of contralateral side as a control when appropriate – and retrospective design.

Our results are similar to recently published series (Virani et al. 2017) (Shannon 2018) and a systematic review of earlier studies (Githens 2014) regarding outcomes and complications, though the flexion arc is better in our series (Table 4). Considering studies which also included younger patients (Doornberg et al. 2007) (Singh et al. 2019) (Ellwein et al. 2015), the DASH scores have been similar to the respective population normal values (Aasheim and Finsen 2014). The MEPS results (85 - 91) and flexion arc (90 – 112) have been quite uniform regardless of the age of the patients.

Our <30 days and one-year mortality rates, about 5% and 10% respectively, were similar to the 2,2% and 9,1% which have been reported from a large database study from New York, USA (Lander et al. 2019). Another large database study (Medvedev et al. 2017) reported low <30 days mortality rates, 1/216, which, considering the low event rates, is similar.

In our series, 11/39 patients had at least one reoperation. Five were minor implant removal procedures related to tension band irritation, which is lower, but similar to rates of implant removal after olecranon fracture surgery with tension band or plate fixation (Claessen et al. 2016) (Ellwein et al. 2020). Overall, the complication rates are very similar to what others have reported (REF Githens), though comparisons are difficult due to varying reporting and classification of complications.

Whether locking plates offer a true advantage over non-locking constructs remains unclear. Our clinical experience, which is unfortunately hard to explore robustly, is that locking plates allow a stable osteosynthesis in more comminuted fractures than non-locking plates. There also was a consistent difference of about 20 degrees more flexion in our series to previous studies. Whether this is due to the new plate technology or more aggressive rehabilitation or some other factor cannot be reliably answered. There were no complications specific to locking plates, and in contrast to some series (Ellwein 2015), the rate of fixation failure was low in our series.

Even though comparisons to TEA cannot be made from our study, considering the more benign complication profile of ORIF, we think our results support the strategy of treating fractures amenable to fixation primarily with ORIF and reserving TEA for the very comminuted fractures and as a second-line option should the primary ORIF fail. During the study period, we used primary TEA for five patients (all with C3 type fractures). However, it has to be noted that our results are from a high-volume trauma center with upper extremity surgeons experienced in both acute trauma care and elective arthroplasty – in different settings the available expertise has to be considered.

Topics for future research include how to avoid reoperations in the form of implant removals. A randomized trial comparing different fixation methods of olecranon osteotomies, perhaps including all-suture osteosynthesis (Phadnis et al. 2017) among the treatment options would be clinically relevant, and considering the large proportion of patients who undergo implant removal, also likely feasible. We think that an RCT comparing ORIF to TEA is unlikely to be fruitful due to the rarity of these injuries and the similar results in the one published RCT (McKee et al. 2009) and non-comparative series. The required large sample size to show superiority is likely to be unfeasibly large, and in the light of our and previous results, obtaining superior results with a TEA to locking plate ORIF in C1 and C2 fractures seems very unlikely. The complication profiles and possible predicting factors might be assessed through registry studies or large, multi-center retrospective studies.

6 Conclusions

Our results indicate that geriatric "reducible" distal humerus fractures can be treated reliably with ORIF in a high-volume trauma center using anatomic locking plates. The expected result is return of function allowing activities of daily living, with some residual pain and a moderate extension deficit.

7 Contributions

TL and MS designed the study
KK and TL extracted data from the patient records
KK performed the follow-up examinations
KK, TL and MS reviewed the radiographs
KK and TL drafted the manuscript which MS critically reviewed

8 Acknowledgements

We deeply thank our research nurse Leena Caravitis for help with the study. We are grateful to our chief surgeon and associate professor Mika Paavola for critical comments on the manuscript and our surgeon colleague Dr. Tomi Simons for linguistic support. We also thank our colleagues at Helsinki University Hospital who performed the surgeries and the physiotherapists who were responsible for the rehabilitation of the patients.

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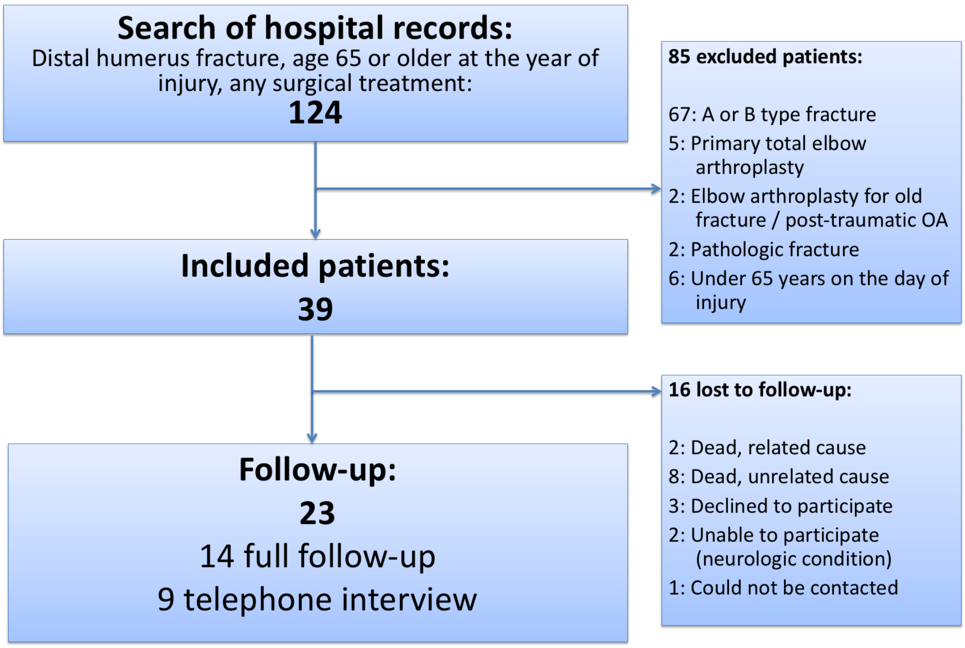
10 Competing interests

All authors declare no support from any organisation for the submitted work; no financial relationships with any organisations that might have an interest in the submitted work in the previous three years; no other financial relationships that could appear to have influenced the submitted work.

11 Data sharing

The original pseudonymised data workbooks are available from the authors on a reasonable request.

12 Tables and figures:



12.1 Figure 1: The study flowchart

	all	OES data	follow-up visit	not available
Number	39	23	14	16
Age at the time of injury*	75.9 (65.3-90.2)	75.0 (65.3-86.4)	74.2 (65.3-82.8)	77.2 (65.5-90.2)
Female	30	20	13	10
Fracture type				
C1	22	15	8	7
C2	4	4	2	0
C3	13	4	4	9
Open fracture	10	3	1	7
Mechanisms of injury				
Simple fall	31	20	12	11
Fall (<3m)	3	1	0	2
Fall while cycling	4	2	2	2
other	1	0	0	1

* mean (range)

12.2. Table 1: Patient and treatment characteristics by follow-up status

Primary outcome, N=23

		Injured arm
OES pain	score	83 (17; 44-100)
OES function	"	83 (17; 44-100)
OES social-psychological	"	79 (20; 31-100)
OES Total	"	81 (15; 46-100)

Secondary outcomes, N=14

		Injured arm	uninjured arm	p ‡
Active arc of motion	degrees	119 (19; 75-145)	146 (8; 135-160)	<0.0001
Extension deficit (active)	"	22 (14; 5-60)	1 (6; -5-15)	<0.0001
Maximum flexion (active)	"	141 (6; 130-150)	148 (5; 140-155)	0.003
Active forearm pro-supination arc	"	177 (14; 150-200)	175 (17; 140-200)	0.7
Forearm pronation (active)	"	91 (19; 70-100)	90 (12; 60-110)	0.9
Forearm supination (active)	"	86 (12; 60-100)	85 (16; 50-100)	0.9
MEPS	points	85 (17; 50-100)	100 (1; 95-100)	0.003
MEPS categories: excellent ≥90 / good 87-89 / fair 60-74 / poor <60	number per category	6 / 4 / 3 / 1	14 / 0 / 0 / 0	
qDASH	points	19 (16; 2-43)		
Subjective satisfaction	NRS 0-10	9 (1; 7-10)		

Data given as mean (SD; range) or numbers

‡ p comparing injured to the uninjured side

12.3 Table 2: Outcomes

Number of surgeries	Number of patients	Reason for reoprations and description of treatment
1	28	primary operation only, no complications
2	5	Implant irritation: Late removal of tension band
	1	Implant irritation: Late removal of tension band and plates
	1	Nonunion of olercanon osteotomy: Reosteosynthesis (good result: OES pain 94, function 100, S-P 100, Total 98)
	1	ORIF failure by 6 weeks: TEA (with modest result: OES pain 56, function 75, S-P 50, Total 60)
3	1	Technical difficulties in first surgery: A revision of failed ORIF, TEA at nine months from the injury (with a good result: OES pain 100, function 100, S-P 75, Total 92)
	1	Postoperative wound dehiscence: Wound revision and removal of olecranon plate five months from injury (wound healed, no outome data, patient died during the follow-up period)
10	1	Deep infection with osteomyelitis: Removal of implants, multiple revisions, resection of osteomyelitic bone and eventually the joint. Led to an almost painless, but poorly functioning elbow (OES pain 81, function 44, S-P 31, Total 52)

12.4 Table 3: Numbers of surgeries and reasons for reoperations. Outcomes are shown for patients who required non-implant removal reoperations related to the fracture treatment.

Article name (year)	Number of patients	Number at follow-up	Patient age years	F-U years	Fracture AO types	Only locking plates?	MEPS	DASH	Flex-Ext Arc	Sup-Pron Arc	Country
Githens et al (2013) Meta-analysis	-	292	75,1*	3.6	B and C	No	87,5	35,2	100	-	Multiple
Virani et al. (2017)	63	41	66.4*	3.2 (2.2-6.8)	C	No	85	21,4 #	105	156	India
Shannon F et al. (2018)	21	16	78 (70-84)‡	4 (1-8)	C	Yes	91	19	97	147	United States
Our study	39	23 (14+9)	79,1 (69,1-93,4)‡	3.2 (1-6.2)	C	Yes	85	19	119	177	Finland

Data presented as numbers, means, means (range). F-U = follow-up
- = data not available
DASH is reported arm-specifically, the value of the injured arms was tabulated
* unspecified , ‡ at follow-up

12.5 Table 4: Outcomes in studies of similar patients

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STROBE Statement

Checklist of items that should be included in reports of cohort studies

	Item No	Recommendation
Title and abstract	1	+ (*a*) Indicate the study's design with a commonly used term in the title or the abstract
		+ (*b*) Provide in the abstract an informative and balanced summary of what was done and what was found
Introduction		
Background/rationale	2	+ Explain the scientific background and rationale for the investigation being reported
Objectives	3	+ State specific objectives, including any prespecified hypotheses
Methods		
Study design	4	+ Present key elements of study design early in the paper
Setting	5	+ Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection
Participants	6	+ (*a*) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up
		(*b*) For matched studies, give matching criteria and number of exposed and unexposed
Variables	7	+ Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable
Data sources/ measurement	8*	+ For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there

		is more than one group
Bias	9	Describe any efforts to address potential sources of bias (no efforts were made)
Study size	10	+ Explain how the study size was arrived at
Quantitative variables	11	+ Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why
Statistical methods	12	+ (*a*) Describe all statistical methods, including those used to control for confounding
		+ (*b*) Describe any methods used to examine subgroups and interactions
		+ (*c*) Explain how missing data were addressed
		+ (*d*) If applicable, explain how loss to follow-up was addressed
		(*e*) Describe any sensitivity analyses (no sensitivity analyses were made)
Results		
Participants	13*	+ (a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed
		+ (b) Give reasons for non-participation at each stage
		+ (c) Consider use of a flow diagram
Descriptive data	14*	+ (a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders
		+ (b) Indicate number of participants with missing data for each variable of interest
		+ (c) Summarise follow-up time (eg, average and total amount)
Outcome data	15*	+ Report numbers of outcome events or summary measures over time
Main results	16	+ (*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included (no adjustment)
		+ (*b*) Report category boundaries when continuous variables were categorized
		+ (*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period
Other analyses	17	+ Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses (No iteraction or sensitivity analyses were done)
Discussion		
Key results	18	+ Summarise key results with reference to study objectives

Limitations	19	+ Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias
Interpretation	20	+ Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence
Generalisability	21	+ Discuss the generalisability (external validity) of the study results
Other information		
Funding	22	+ Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based

*Give information separately for exposed and unexposed groups.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at http://www.strobe-statement.org.